MEDICARE PAYMENT ADVISORY COMMISSION

PUBLIC MEETING

Ronald Reagan Building
International Trade Center
Horizon Ballroom
1300 13th Street, N.W.
Washington, D.C.

Wednesday, January 16, 2002
9:34 a.m.
And
Thursday, January 17, 2002 - begins page 20
8:33 a.m.

COMMISSIONERS PRESENT:

GLENN M. HACKBARTH, Chair
ROBERT D. REISCHAUER, Ph.D., Vice Chair
BEATRICE S. BRAUN, M.D.
SHEILA P. BURKE
AUTRY O.V. "PETE" DeBUSK
ALLEN FEEZOR
FLOYD D. LOOP, M.D.
RALPH W. MULLER
ALAN R. NELSON, M.D.
JOSEPH P. NEWHOUSE, Ph.D.
JANET G. NEWPORT
CAROL RAPHAEL
JOHN W. ROWE, M.D.
DAVID A. SMITH
RAY A. STOWERS, D.O.
MARY K. WAKEFIELD, Ph.D.

AGENDA item:
Paying for new technology in the outpatient prospective payment system - January 16, 2002
Chantal Worzala, Dan Zabinski

DR. WORZALA: Dan and I are here to discuss how Medicare pays for new technology in the outpatient setting. I'm going to very briefly summarize the issues, which we've presented before. Dan will then discuss how we propose to address those issues and present a draft recommendation for your consideration.

Medicare has an obligation to ensure beneficiary access to needed new technology by paying adequately for it. However, it's difficult to set payment rates for new technology because there is very little data available to determine costs. And the two basic payment approaches we use, bundled payment and cost-based payment, are both inadequate. A bundled payment has the potential to limit diffusion of new technology by underpaying for it at the margin. However, a cost-based payment has the potential to increase use of technology unnecessarily, leading to excess spending and possibly inappropriate use.

This is a problem for Medicare in all of its payment systems and, as we discussed at the last meeting, it's also a problem that can be extended beyond new technologies to those for which Medicare is the only or the major purchaser. However, we propose to address only the treatment of this issue in the outpatient PPS at this time. We recognize that the Commission may wish to explore the issue and extend it to other areas in the future.

The outpatient PPS tried to address the issue of how to pay for new technology inputs by implementing the pass through payments which are meant to cover the incremental costs of new technologies when they are used. However, the payment mechanisms that are used have the potential to lead to overpayments. By paying hospitals charges reduced to costs for medical devices, the system provides incentives for manufacturers and hospitals to increase their prices and charges. And by paying 95 percent of average wholesale price for drugs and biologicals, Medicare generally pays more than hospitals' acquisition costs for these products.

Overstated charges will also lead to distortion of relative weights when the costs of pass through items are incorporated into base payments. Services using pass through items will be relatively overpaid while other services will be relatively underpaid.

At the last meeting we presented three options to address these issues. Taking into account your discussion of those options and comments by others, Dan will now present our thoughts on how to address them.

DR. ZABINSKI: After considering the commissioners' comments on the options we presented at the December meeting, Chantal and I have concluded that the best course of action is to base pass

through payments on national payment rates. For devices, this would include a fee schedule with national rates which would replace the current hospital-specific payments. For drugs, the Secretary should be allowed to base payments on alternatives to average wholesale price or AWP.

Using national rates like this would reduce the potential to overpay for pass through technology. This is because the fee schedule would eliminate hospitals' incentive to raise charges for devices which is present under the current mechanism. Also, the Secretary would have the opportunity to base pass through payments for drugs on alternatives to AWP that better reflect what hospitals actually pay for drugs.

An issue we emphasized that Chantal touched on earlier is that good data for setting fee schedule rates are very difficult to come by. After all, one of the reasons that the pass through system exists is because CMS did not have adequate cost data on new technology to incorporate them into the APC base payment rates.

Chantal and I, as well as others on the MedPAC staff, have considered several possibilities for setting rates. We believe the best option is to use manufacturer's estimates of how much hospitals will pay for new technology net of any discounts or other reductions. This information could be used in place of AWP for drugs, as well as in a fee schedule for devices.

We recognize that this would give manufacturers an incentive to inflate reported costs, and there's nothing in the pass through system that would dampen this incentive. For example, if the pass through technology had to pass a cost benefit test, then there would be less incentive to inflate reported costs. But no such criterion exists in the pass through system.

However, CMS could audit the cost estimates for manufacturers to reduce this problem. Furthermore, this option does have some advantages. First, there would be little additional burden on CMS because manufacturers are already required to include this information on applications for pass through eligibility.

Second, hospitals would have no incentive to inflate charges, which they have under the current mechanism. Therefore, CMS would have better data when it folds the costs of new technologies into the base payment rates after pass through eligibility is used up.

Finally, this option would introduce consistency with how pass through payments are determined for inpatient care, which have an upper limit on the prices paid by hospitals as reported by manufacturers.

Finally, we have drafted this recommendation that reflects our analysis of the issues in the pass through system and the issues that the commissioners have raised at previous meetings. In particularly, we believe that Congress should replace hospital-specific payments for pass through devices with national

rates to be set by the Secretary. Also, the Congress should give the Secretary authority to consider alternatives to average wholesale price when determining payments through pass through drugs and biologicals. That's it.

DR. NEWHOUSE: I am reluctant to accept that this is the best option. Essentially the argument is that -- first of all, we're going from cost-plus basically to cost. The whole thrust of policy here in the last 20 years has been to try to get rid of cost reimbursement. And for us to now recommend that here is very hard for me to swallow.

I suggest the following modification. It seems to me where the problem with having this in the APC is the greatest is where, first of all, there's a substantial dollar amount for the drug or device. So that if the payment for the APC is $500 and this piece of technology costs $500 it's going to be hard to get it in. If it costs $15 it's probably not a big deal.

And secondly, where the Medicare market share for this product is high, if it's not high then CMS can observe what's going on in the private market and just pay that.

So I think rather than pay cost it would be better to say leave it in the APC. If you want to, put an S&TA in the APC to cover this, just like we do in the PPS. Except when the dollar amount is above X and the share is above Y. Now what X and Y are, I don't think I'd want to say now without seeing some distributions.

And then, in those cases, I think I would try to set the fee based on some return to equity for that product. But the intent would be to try to minimize the number of cases when I have to do that.

MS. BURKE: Joe, don't you create the incentive to go to X?

DR. NEWHOUSE: Don't you what?

MS. BURKE: First of all, I don't disagree with your premise, but A, I wonder how complicated we can expect a relatively unsophisticated system to get in payment. But B, a model that has you setting an X and a Y just assumes everybody is going to move to X if they can.

DR. NEWHOUSE: Depends on, particularly if I don't model the -- I'm not sure it does. I'm thinking of devices that are pretty specific to the elderly, or drugs. In Medicare erythropoietin would be the extreme case. If I have a device, a disposable of some sort, that's probably not very elderly specific and I'm probably not going to take it off the non-elderly market just to get to X.

MS. BURKE: So in that case you'd go to the market, I understand. It's the non-market base that when there's not another market, when you're essentially creating a market and essentially setting anything above -- it's the old if it was below $50 million it was a rounding error. We used to star it. It was like well, what's the number? The number is $15. Okay, well I'm at $13.50, I'm going to move to $15.

In setting the market if you set an arbitrary number, it seems to me, you create an incentive for people to move --

DR. NEWHOUSE: That's why I'd want to look at the distribution. You may get some gaming in the neighborhood of X. But the alternative, to me, is even worse. Then why don't I just mark up my price a whole lot and take it to the bank?

MR. HACKBARTH: I'm going to need to go back for a second because I think I'm confused. The option that's been recommended by the staff is manufacturer's estimates of what a hospital is paying net of discounts. I assume that's private patients as well as Medicare patients. So it's what hospitals have been paying for these devices regardless of whether it's going into a Medicare patient or a private patient, right?

DR. NEWHOUSE: That was true when we had cost reimbursement for all hospital costs.

MR. HACKBARTH: So where there's an active private market, those rates that they pay may be influenced by pressures from managed care, hospitals who are saying we can't afford to pay a lot for this device because we're not getting a lot from the health plan. So there's some market pressure to hold those rates down.

And you're worried not about that case, Joe, but about the case where these are pretty specific to Medicare beneficiaries and there's not much market pressure?

DR. NEWHOUSE: That's right. But upstream of that I'm worried about -- we probably first ought to decide whether we want to pay on the basis of cost. Maybe you can't decide that without saying what is the option that you're going to pay under.

MR. HACKBARTH: What gets us into this conversation, as I understand it, is we don't have any data. And so we're grasping for something to hang our numbers on and something that can be administered, as opposed to the hospital-specific charge-to-cost rations, the staff is suggesting let's look at what was actually paid.

I don't think with any pretense that it's perfect, but perhaps better than the cost-to-charge ratio.

MR. MULLER: I understand, Joe, to use the analogy to the inpatient program, which I think you made, and using your X and Y categories, you're basically trying to reduce the number of exceptions so it becomes more of an outlier policy in the inpatient program. In part, because I'm also assuming that under the current law that it's all budget neutral, then in that sense having fewer exceptions is what you're looking at here.

DR. NEWHOUSE: Yes. The other difference with the inpatient side, as has been brought out in the earlier discussions, was frequently these kind of costs are going to be larger relative to the payment for the category than they are on the inpatient side, so the deterrent to not put it in there will be correspondingly greater.

MR. HACKBARTH: So, Joe, are you suggesting that for the

devices that are used by private patients as well as Medicare that there not be any pass through at all? That they be immediately incorporated in APC rates?

DR. NEWHOUSE: Yes, or that we do what we do on the inpatient side which we've put an add on into the APC rates for something that's called new technology. But that's just global because we can observe a price there, or we will shortly, and that's about what we should pay.

MS. BURKE: But, Joe, arguably the difference between the inpatient and the outpatient is what it is, which is on the inpatient side you have a much bigger buffer. But on the outpatient side you're going to have a far narrower buffer. So that incorporating it in a general way into the raid may still leave such a disincentive for the incorporation of the new technology in the short term as to be at odds --

DR. NEWHOUSE: That's why this quasi-outlier scheme needs to be quite a bit bigger, I think, than it would be on the inpatient side.

DR. WORZALA: On the issue, I don't know what we could do about Medicare share. I guess we could ask manufacturers to tell us what they expect the market to be.

On the issue of a dollar, we did sort of talk a fair amount about setting a dollar threshold. And if I can direct your attention to our briefing papers, there's a text box on eligibility for pass through status that begins on the bottom of page seven and continues on page eight. The clinical criteria for a pass through item on the outpatient side have been tightened considerably in a final rule issued, I believe November 2nd of last year. That is described on page eight.

On page nine, all the way at the bottom are the cost criteria. What are currently in place by CMS are all relative cost criteria. There is no actual dollar amount threshold. We did contemplate whether or not we would want to introduce the notion of a dollar amount threshold, but we had this problem that Sheila raised of well, once you state a cost how about that, everything costs that or more.

And then there was this issue of how do you actually update it over time? I expect you can collectively think of ways around those and we would certainly be willing to hear it.

But let me just clarify what the existing cost criteria are. Again, these are all relative. The first is that the average cost -- and again we're talking about categories here, this becomes nothing but more and more complicated. This is on the device side and we have categories of devices, so it's not a single item but it's multiple items that serve the same purpose.

So the estimated average reasonable cost of devices in the category must exceed 25 percent of the payment amount in the applicable APC. So it has to represent at least a quarter of the total estimated cost.

And then the estimated average reasonable cost of devices in

a category must exceed the cost of the device it replaces by at least 25 percent. So new technology is 25 percent more expensive than old technology.

And then the final is that that 25 percent difference represent at least 10 percent of the base payment rate.

So it is true, for example at the moment we have catheters as something eligible for pass through payments, just regular catheters used during surgery, implemented and taken out. That is a relatively low cost item where you can actually have a lot of things coming through and they probably shouldn't be coming through the pass through. But given the revised clinical criteria, I doubt that that sort of thing will be coming up for eligibility in the future. And it's likely -- I can't say this for sure -- but given these relative criteria it's likely that mostly only very expensive items will go through.

And again I actually do have a hip pocket slide that is a recommendation that says put in place a dollar amount threshold. We can certainly go down that road but I wanted to let you know both what the current criteria are in terms of cost and also some of the issues surrounding introducing that.

DR. NEWHOUSE: May I respond to this? First, on how to estimate the share. I would actually I think have a panel of MDs say to what degree is this device going to a disease or diseases of the elderly. You're going to make some mistakes, but as a rough cut you'll probably get it where it's basically mostly elderly.

On Sheila's issue, which you also raised, of if I set a dollar threshold I raise it so everything is at the threshold. I think that applies to the share, as well. So I don't see that the share gains.

On increasing it over time, I would in fact index it to probably the GDP deflator, but you can put in some kind of indexing on a dollar amount.

DR. ROWE: I thought I understood this, but the more we discuss it the less clear I am. Let me just make sure that I got this wrong, because I want to make sure I got this wrong.

If I am a person who makes a device that is of particular use for the elderly and relevant to a certain APC, and the APC cost is $400, and my device costs $50, the hospital has to eat it. But if I increase the price of my device to $125 then it's a pass-through. The hospital doesn't have to eat it and I get paid directly by Medicare. Is that right?

DR. ZABINSKI: The hospital pays you, the device manufacturer. The hospital gets an increased payment.

DR. ROWE: But Medicare is paying more, the incentive is to increase the thing so that it gets to the pass-through. I'm wrong in as much as I don't get the check from Medicare, I still get the check from the hospital. But I'm right --

MR. MULLER: The check goes to the device, it doesn't go to you. I mean, you countersign it and move it on.

DR. ROWE: I understand, but the incentive is to dramatically increase the price to get it above the threshold for being a pass-through. It saves the hospital money, which is fine. But increases the Medicare program's cost.

MR. MULLER: No, it doesn't because first of all, the APCs become budget neutral so they get recalculated. Maybe not in your hospital --

DR. ROWE: But I'm ripping off the system, is my point.

MR. MULLER: The $125 you pass on to the device manufacturer.

DR. ROWE: But I'm the device manufacturer.

MS. BURKE: Jack, here's the alternative. You create a device, the device costs $125. The APC is $400. We don't adjust it. It's a new device we've not seen before. The APC doesn't have it in the base calculation. And we can chose to eat it or not use it. That's the alternative.

DR. ROWE: I'm not attracted to that either, but you understand what I'm saying.

DR. NEWHOUSE: But if the device has a relatively low Medicare share, the hospital is probably going to stock it for the non-Medicare market. It will probably then filter in.

There's no good answer here. Chantal is certainly right about that. The issue is what's the least of evils.

DR. REISCHAUER: So we don't worry about that. Now what are we doing about the one that has a high Medicare share? What's your answer again?

MS. BURKE: He's going to set a price.

DR. REISCHAUER: But the price is going to be an absolute dollar level, like $75, as opposed to X percent of the APC?

DR. NEWHOUSE: Yes.

MS. BURKE: That's what he's proposing.

DR. REISCHAUER: Why shouldn't it just be X percent of the APC? It strikes me that if it's $75 --

DR. NEWHOUSE: Suppose the APC is $10,000.

DR. REISCHAUER: So it's easier to swallow $100 device in a $10,000 reimbursement than it is in a $400 reimbursement, from the standpoint of the hospital.

MS. BURKE: Then it won't meet the threshold.

DR. REISCHAUER: I'm just saying why do you need two things? I would think that what you would want to have is -- big depends in a sense or on how big it is relative to the payment the hospital is getting. That's all.

DR. ROWE: But if there's a $10,000 payment -- let's use the extreme example. And I'm still making my device, I'm now a device manufacturer. And it's $100 device but I decide to charge $2,550 for it instead of $100. It makes the pass-through, I get paid all that, and that's outrageous. And if there's a sole source and doctors really want to use it, that is what's going to happen. So we've got to avoid that somehow, Bob.

MR. DEBUSK: Manufacturers don't do that, Jack.

[Laughter.]

DR. ROWE: I withdraw my concern.

DR. REISCHAUER: There is a Defense Department toilet seat threshold, and even Pete with a straight face wouldn't charge $2,500 for this $100 device.

DR. ROWE: Then I don't have a problem. If everybody's comfortable with it, fine. I just was listening to what I was hearing and I was concerned that there was going to be this incentive to raise the prices.

MR. SMITH: Of course you're right. And Pete, with all due respect, in this closed market if you're sent a signal that X is okay, that's what you'll charge. It doesn't seem to me that either the percentage threshold or the dollar, Joe, get us over that. We are setting a floor for a bunch of devices that we don't know about, that we don't know how much they cost, but we can tell you what the price is going to be in Medicare-dependent markets.

DR. NEWHOUSE: Remember, if you get over the threshold, HCFA sets the price. It's not your price anymore.

MR. HACKBARTH: But on what basis?

MS. BURKE: Joe's view is CMS sets the price.

DR. REISCHAUER: You get over the threshold with a $2,500 price and the HCFA comes back and says $100?

MS. BURKE: Yes, that would be about right.

[Laughter.]

DR. REISCHAUER: I don't know why you have to have the dollar value, is all I'm saying.

DR. NEWHOUSE: I'm trying to minimize the amount of price setting that's going on. You've got to meet two tests. Even if I have a 70 percent share, if it's a very small cost I'm not too worried about the incentives to adopt it. That's why I've set the dollar threshold.

But you can have one threshold, you'll just wind up setting more prices that way.

MR. HACKBARTH: But in the case of something, Joe, that comes in under the threshold, it's got to be incorporated in the APC. You still have to have a number there, don't you?

DR. NEWHOUSE: No.

MR. HACKBARTH: You just eat it.

DR. NEWHOUSE: You just swallow it. You treat it like you do the inpatient side.

MS. BURKE: And it happens over time.

DR. NEWHOUSE: Then over time you'll get some numbers and you can feed it in.

MS. BURKE: It's the extraordinary entry that's the issue, not the routine integration. It's the extraordinary entry, a new event at a particular time that's significant enough to deter its use if, in fact, it's not accommodated. That's what Joe's concerned with. What's the outlier, is the issue? It's not the routine that we adjust for over time.

MR. SMITH: But I think Jack's imitation of Pete suggested that if there is a trigger, we're going to have more prices at that trigger. I don't think we know anything that suggests that that isn't true.

MR. DEBUSK: And competition comes into play. Can we back up just a minute and get just a little bit more grounded. Let's go back and look how we got into this $1.7 billion over the allocated 2.5 percent of the $17.5 billion. Chantal, that was done very well, the chapter on this, in my opinion.

You know, you go back and look, we come along with BBRA, BIPA, and we try to put more dollars into a bad situation to try to make up some of these dollars to keep that hospital alive, especially with the outpatient piece. And we kept reaching back and taking devices out of what was already figured in the rates in '96, and we pulled them forward and started paying for them as if they were new technology.

And there were two or three inputs, and we just drove that cost way up. And then you know the results we got and so now we're addressing that.

I think, when all of this goes back into the APC code this fall, and we truly look at new devices going forward, it's not going to be that bad. I don't think there's that big of an issue.

Now going forward, I sort of like the comment here, pass-through devices with national rates to be set by the Secretary. Of course, there's multiple things that come into that, but they're in a far better position to go forward and decide what some of this new technology, like some of these stents that we talked about briefly last time, which is quite expensive. But this is tremendous new technology that all of us are going to want if we're requiring something of that nature, and these pacemakers and what have you.

But they will be in a lot better position to look at that, to address what Medicare should pay for that, I would think. I think this recommendation is put together pretty well.

But there's always going to be this issue that Joe's talking about here. How do you keep that target from being set up here and saying here's the target, so everybody's going to go to the target?

MR. HACKBARTH: So let me see if I can summarize what I've heard. There seems to be agreement between the industry and CMS, as I understand it, that the huge bulge of things coming through the pass-through that happened this year isn't going to happen in the future, that we're talking about a much smaller number of devices.

CMS proposed a series of threshold requirements, cost and clinical, that Chantal reviewed just a minute ago. You're saying those thresholds are too low?

DR. NEWHOUSE: No, I said I don't know until I see a distribution. But again, let me say for the people who are

worried about it going to the threshold, it depends on what the alternative is. But remember, if you're over the threshold, you get your price set. So the incentive is to stay under the threshold.

Then the issue is what were your incentives in the alternative world, where there was no threshold? It doesn't seem to me that the threshold distorts your decisionmaking.

MR. HACKBARTH: But, Joe, the way I understood your initial point was that you wanted to limit still further the number of devices that are subject to the pass-through by creating a threshold and saying we're only going to do this if it's relatively large and it's very important for Medicare.

DR. NEWHOUSE: Over time you're going to get -- you'll accumulate a stock of things that are pretty much Medicare specific, in which case I've got the problem back to the device manufacturer of how does this thing price? It seems to me that's an open invitation to raid the treasury.

MR. HACKBARTH: But was my description accurate? You want to further limit the number of devices subject to the pass-through, saying all the small stuff is going to go straight into APC. We're going to set a high threshold to limit it.

DR. NEWHOUSE: Yes.

MR. HACKBARTH: Then in that case, when we've got those few devices left, the price we set is going to be done by what mechanism? How are we going to pull that number out of the hat?

DR. NEWHOUSE: I think I would do it as a return on equity.

MR. HACKBARTH: How are we going to know?

DR. NEWHOUSE: You would take the share of the manufacturer's total line of business that the Medicare business represents -- which may be high if I'm a startup with a single device that's mostly Medicare. And you would say I'm going to pay whatever number you pick, 15 percent, 20 percent return. I'm going to set the price to achieve that.

MR. HACKBARTH: But how do you know what their investment was? If it's a multiproduct firm --

DR. NEWHOUSE: This is how the British run their drug price regulation and they've done it for a number of years and it seems to work, by all accounts I hear.

The alternative, it seems to me, is you ask you set any price here for the new technology. Or you just do cost, which I don't think you can do in these cases where there are costly items and there's a big Medicare share.

DR. ROWE: The second part of my concern about this had to do with migration of activities from the inpatient to the outpatient in order to try to take advantage of this pass-through. This business about endovascular procedures are now very common and stents are being used and they're now coated with antithrombotic pharmaceutical agents or antibodies, and $10,000 is not an unreasonable -- well, I don't know if it's reasonable or not but it's a common price for these items. And if it's done

in the inpatient it's in the DRG and the hospital eats it and it's very expensive and very difficult. But patients clamor for it, et cetera, et cetera.

On the other hand, now if you have an ambulatory surgery facility that's sort of defined as part of the hospital and the patient comes in, these procedures, the patient has them and goes home and they don't stay overnight, it's being done now in the outpatient. Does this mean that that price now is then pushed over to Medicare and we're going to see all these cardiac caths and aortic procedures and everything all of a sudden now defined as outpatient?

I'm just trying to think -- and maybe that's right. Maybe it's okay because even if we pay $10,000 for the stent in the outpatient APC, the rest of the cost is so much lower than the inpatient cost would have been that maybe in the long run it doesn't cost more. I don't know. And what's better for the patient? I don't know.

I'm just trying to understand whether or not we're creating rules that are going to create financial rather than clinical incentives to migrate the care of our beneficiaries from one site to another. And that's not what we're about, presumably, so we should be aware of that.

MR. DEBUSK: Sometimes, Jack, maybe what we have is not broken as badly as we think it is.

MR. HACKBARTH: But in the case of a device that's used for inpatient care as well as outpatient, and the hospitals are constrained on the inpatient side, presumably the negotiation has a different flavor to it than if there's a pass-through payment.

So if, in fact, there's a big inpatient market for it, presumably they're bargaining as best they can for the lowest possible price from the manufacturer. You really only worry about the price where they can somehow pass it through and don't have to negotiate.

DR. ROWE: No, what they're doing is they're paying the price demanded by the manufacturer, and they're losing money on that case because if they don't do it their cardiologists will leave and go to another institution or that aortic surgeon, et cetera, and this is cutting edge and the patients demand it, et cetera, et cetera. That's what they're doing.

MR. MULLER: As we learned last month, just in big urban centers.

[Laughter.]

DR. ROWE: I don't know that it's a problem. Just we should think it through.

DR. WORZALA: Just on the issue of setting, a point of clarification. There is also a technology payment that will soon be in place on the inpatient side, as well. The clinical criteria for eligibility for a technology are very similar between the two, if not identical. The cost criteria are different and the payment mechanism are different.

We actually, with our recommendation, were trying to introduce a little bit of similarity across the two settings because on the inpatient side they make these additional payments based on the cost. But the payment is limited by "average national price" which will be determined by CMS. And in my conversations with CMS they say well, we'll have to take it off the application and we'll audit that information.

So part of what we're trying to do is introduce commonality across settings so that we have a national payment rate rather than a payment based on hospital cost. We can make the point more clearly. We do try to do that.

MS. BURKE: Let me understand. Is there a compelling reason for us not to use the same pricing mechanism?

DR. WORZALA: For one thing, we can't assume that the technologies will be exactly the same.

MS. BURKE: Irregardless of whether they are the same, whether they're both stents or whatever. But is there a reason not to use the same strategy?

DR. WORZALA: I think it comes down to the size of the bundle and the fact that on the outpatient side your technology may well represent a larger share of the total cost. And on the inpatient side you have a much broader --

MS. BURKE: No question.

DR. WORZALA: So that's the rationale.

MS. BURKE: But that's just an explanation for the margin of error. I mean, that's how you protect against margin of error. That isn't the fundamental question of how you determine the price.

DR. WORZALA: The price limit, I would agree, it's exactly the same. But what they're doing on the inpatient side is to take the cost of the actual case and say is that -- I may get this wrong, but bear with me on the details. It is in your briefing paper in one of the text boxes.

My recollection is that they take the cost of the case as reported. They determine whether that's greater than one standard deviation above the geometric mean cost of case in that DRG. And then they pay half of the difference, half of the excess, up to a limit. And that limit is the average national price, which they will determine in negotiation with the manufacturers.

MS. BURKE: Let's stand back for a second and look at this. What Joe suggested -- and I'm open on what the solution to this is -- is essentially you look at it arguably as compared to something. In this case, you look at it as compared to the total case cost, which presumably is much larger than the APC. One scenario has us comparing it to the APC, which is part of one of the scenarios here.

So my thought is just if we're going to go down some road, why not at least have similar characteristics in both roads? I mean, the basis will be different. But the process, there's no

particular -- that I can hear -- compelling reason not to use a similar process knowing that the basis will be different.

I mean, we know that the margin is greater on the inpatient side because you've got a bigger base. But if you do it as a comparison to the APC rate, you've got a smaller base. But the principle is the same.

MR. MULLER: I would say, the paper was very good on this. This pass-through system is way too big, the 13 versus the two. It's incredibly administratively complex in a system that's already complex and hard to understand. So trying to get the number of pass-throughs to as small a number as possible I think is an objective everybody has, so it can get back into the regular system.

So insofar as Joe's recommendation gets us there, I second it. I think trying to get the number of pass-throughs down to a low number, as opposed to the very high numbers right now, is a very appropriate thing to go for because we already have an overly complex system that's been difficult to implement.

DR. NEWHOUSE: You can get to a smaller number. The issue is once you've gotten to the smaller number, then what do you do with the group that's in the small number? So what I'm trying to do is trying to minimize the amount of price setting for that small group which will grow larger, of course, over time potentially.

MR. HACKBARTH: Let's just review where we are. That was a helpful comment, Ralph. So let me phrase this as a question. Do we have agreement that we ought to continue a pass-through but try to make it smaller than it's been? That's where we left it last meeting. Is everybody still on board for that?

DR. NEWHOUSE: I'm not sure. If I stuff it into the APC then there's no longer a pass-through. So there's this outlier thing where there's still a pass-through of sorts.

MR. HACKBARTH: Let me phrase it in a different way. We recognize that outpatient services and devices present some different issues than inpatient because the device costs could be --

DR. NEWHOUSE: There's the same issue on inpatient.

MR. HACKBARTH: But in fact, it has been handled differently in outpatient.

DR. NEWHOUSE: Historically.

MR. HACKBARTH: So are you suggesting do away with any --

DR. NEWHOUSE: I'm with Sheila, apply the same principle.

MS. BURKE: If you're moving to a new system on the inpatient side, my only point is let's try and at least track the theory behind both and then at one point you trigger it, what the margin is, how you fix the price. We can talk about that, but at least in principle, if we're moving to that kind of a pass-through system on the inpatient.

MR. HACKBARTH: But in both cases it involves a supplemental payment for new technology for a period of time.

MS. BURKE: Yes.

MR. HACKBARTH: So maybe we ought to avoid the language pass-through and call it a supplemental technology payment.

DR. ROWE: At a price determined by CMS.

MR. DEBUSK: Yes.

[Simultaneous discussion.]

MR. HACKBARTH: Again I'm trying to figure out where we've got agreement. So whether it's inpatient or outpatient, we're talking about a temporary supplemental payment for some new technology that tends to be very expensive new technology, the exact threshold to be defined. We want to keep it as small as possible --

DR. NEWHOUSE: With a high Medicare share.

MR. HACKBARTH: With a high Medicare share.

DR. NELSON: And a single national rate.

MR. HACKBARTH: And the question that I don't think we've been able to resolve is exactly how to set that national rate. We don't want it inflationary -- we've got to have one conversation, this is complicated enough.

So some sort of an adjustment for new technology with a set rate that is by a means that isn't inflationary. And we want to keep the class that it applies to as small as possible. That's the common ground?

DR. WAKEFIELD: Are we talking about a supplemental payment that's paid in a budget neutral fashion? Does budget neutrality come into play here?

MR. HACKBARTH: That's the current framework, is that it needs to be budget neutral.

DR. WAKEFIELD: So then do we need to be concerned about hospitals that don't have a case-mix that would be using the sort of technology if then the payment for that technology is done in a budget neutral fashion? Then are we distorting some of the payments to hospitals that have a different case-mix?

MR. HACKBARTH: It has redistributive effects.

MR. MULLER: We're trying to keep the class small.

MR. HACKBARTH: Exactly. One of the problems --

DR. WAKEFIELD: So we want to make sure that's clear.

MR. HACKBARTH: That's a reason for keeping it small. One of the reasons it was a big issue this year is because so much flowed through.

MR. DEBUSK: But that's going to be over with. That's sunsetted.

DR. ROSS: Could I just respond to that? Redistribution depends on what you think is the status quo here. If you include in these payments, yes you push resources away from institutions that don't use those new technologies. Failure to do so, however, means you're paying -- you're, as it were, discriminating against the people who do use them.

So it's not redistribution, you've got a distribution problem.

DR. WAKEFIELD: But the point is there is a class of hospital then that's probably going to be adversely impacted, although we're trying to minimize that adverse impact; right? Is that correct? either way.

MS. BURKE: Either way.

MR. HACKBARTH: So if we have agreement on this basic point, then the question I would ask is are we obliged to be specific in exactly how the Secretary ought to set these national rates? Or is, in fact, that maybe beyond our competence?

DR. NELSON: It is.

MR. DEBUSK: It is.

DR. REISCHAUER: But we want to say there's two types of rates he's setting. One, he looks at market conditions because it's not predominantly a Medicare application. And then there's the other, which are heavily Medicare focused. And we punt. We're price-setting but we don't want to admit it.

DR. WORZALA: If we're taking Medicare share -- when we started this, we were thinking okay, we're going to leave eligibility criteria alone because they seemed to be moving in the right direction and focus on the actual payment methodology. It sounds like we also want to be addressing eligibility criteria.

In which case, we would want to draft a recommendation that said something like the Secretary should add consideration of Medicare share to the eligibility criteria? Or the Secretary should add a dollar cost threshold to the eligibility criteria? Something along those lines.

If that's what you want to do, we're happy to play around with those words and bring them back to you. I'm not sure we can do that right now.

DR. REISCHAUER: No, I think eligibility for consideration we go back to Joe's original point, which is is it a dollar value above some minimal threshold, $100 or $200, and a relatively high percent of the APC? Non-swallowable is what we're really looking for.

And then once you've jumped those two thresholds, then you can be considered for these additional payments and you divide everything into two categories. One for which the Secretary can look at market information and come up with a meaningful price. And the other which he'll have to set through -- like he does -- right.

DR. WORZALA: I have a problem with that concept because the pass-throughs are put in place for new technologies for which there is no market information. The concern in the past has been that it's taken Medicare too long to wait for information to set payment rates, so that new technologies weren't being paid for adequately in the interim. So I'm not sure how directing the Secretary to gather market information helps us solve the underlying problem, which is that Medicare was perceived as a poor payer for new technologies in the first years that they're

introduced.

And remember that this is a two to three year additional payment. And one of the reasons we wanted to move to national payment rates was so that the charge data that CMS uses to estimate costs is uncontaminated by the incentive to raise charges to maximize additional payments through the pass-through.

DR. NEWHOUSE: So maybe the eligibility is only on share because that's -- or estimated forecasted share. Because if I set a very high price -- take erythropoietin. If I said $500 a dose instead of $11 a dose initially, that's what ultimately would get folded into the rate. So it's with me forever. It's not just two or three years.

DR. WORZALA: Yes and no. It depends on how the hospitals charge, because it is the charge data that's used for folding it into the rates, not the pass-through.

DR. NEWHOUSE: They're probably not going to charge less than their cost.

DR. WORZALA: True. As we've all said, there is no right answer.

DR. ROWE: We had a longer discussion on this than we had on all the payment --

DR. ROSS: So I guess the question is whether we try to craft a recommendation overnight that meets this or whether we write a chapter that does not have recommendations but lays out the issues and some principles. I was just saying to Glenn that a recommendation as a statement of principle isn't entirely helpful because there's no action to it. We can work through these discussions in the text and that is presumably helpful.

DR. ROWE: Is this required?

DR. ROSS: Under our broad mandate to advise Congress on Medicare payment policy. There's not a specific statutory mandate. I mean, this is obviously one of the live payment issues, as evidence by the discussion.

MS. BURKE: But I wouldn't want our absence to have a specific recommendation to suggest that we don't agree, in fact, that there ought to be a supplemental payment for a period of time that allows the entry of new technology. The debate here is not about that, it's about how we get there. So I wouldn't want there to be any confusion about our desire to go there.

MR. HACKBARTH: I think the principles, if you will, that we agree on are substantive. These aren't airy, abstract ideas. In fact, they reflect some dissatisfaction with the current state of affairs. It's an agreement that there ought to be some supplemental payment but the current mechanism isn't working very well. I think that's important to say, and important to say in boldface, as opposed to buried in the text.

I am not very optimistic that we are going to be able to get too much further in terms of defining with great specificity what the thresholds ought to be and what the price-setting mechanism ought to be. So my inclination would be to ask Chantal and Dan

to come back with a recommendation that captures those broad principles and vote on that tomorrow and leave it at that.

Do people feel comfortable with that? Everybody except for Chantal, and she doesn't count.

DR. WORZALA: I just want to clarify. Is there agreement that we want to move to national payment rates?

MR. HACKBARTH: Yes. The only question is how.

DR. ZABINSKI: You said broad principles, but I'm still not 100 percent sure what the broad principles are. To make sure, I'd like a list of what these things are.

MR. HACKBARTH: Let me try it again. One is that there ought to be temporary supplemental payments for expensive new technology so as not to impede the adoption, non-swallowable technology.

DR. WORZALA: That is recommendation language.

MR. HACKBARTH: So that's number one. Number two is that we ought to limit that class, as far as reasonable, and in the text we can say that the current system, we think, has made the door way too big and there's too much cramming through.

Number three is that when there are items that qualify for the supplemental payment, we need to pay for them with national rates in a manner that is not inflationary and inherently increasing the cost for the program.

I think those were the major items. Am I missing anything?

MS. BURKE: [Inaudible].

MR. HACKBARTH: Given what's happening on the inpatient side that there ought to be some parallelism in what we're doing for the inpatient and outpatient pieces of the puzzle.

MR. SMITH: It seems to me we've also agreed that the limiting tool ought to be relative cost.

MR. HACKBARTH: High cost relative to the APC.

DR. NEWHOUSE: That's the swallowable.

MR. HACKBARTH: That's the correct way of putting it.

DR. WORZALA: Given what we know about the introduction of more stringent clinical criteria, and the cost criteria as they exist, and the predictions by CMS and industry that there will be small numbers going through the pipeline in the future, do we want to further limit beyond what exists? Which is, of course, different than what resulted in the problem of last year and moving forward without a different existing set of criteria.

MR. HACKBARTH: You're saying, Joe, that we ought to say this is in the right direction but not far enough?

DR. NEWHOUSE: If the new erythropoietin turns up, there's some replacement for it. There's a new renal dialysis drug, let's say. The problem is there.

MR. HACKBARTH: Let me just make sure I understand what you're saying. Chantal was saying CMS has moved in this direction to tighten things up. Are we saying they haven't done far enough? Or are we not passing judgment on that point?

DR. NELSON: No, we're not. Just anticipating the future.

DR. NEWHOUSE: If I understand where they've gone, we're saying they may have gone a bit too far in that they're -- I'm sorry. The issue is for the class that's left, how the reimbursement is going to be set?

MR. HACKBARTH: No. They've adopted clinical and cost criteria to try to limit the number qualifying for special treatment.

DR. NEWHOUSE: Right, so once we've limited, then the issue is how do we pay for what's still left?

MR. HACKBARTH: Agreed. But the question I hear Chantal asking is are we making any comment on what CMS has proposed, in terms of clinical and cost criteria? Or are we just not addressing them at all? Is that right?

DR. WORZALA: This would be the issue of adding a cost threshold, for example.

MR. SMITH: They have a cost threshold.

DR. WORZALA: I'm sorry, I meant a dollar amount threshold, excuse me.

MR. SMITH: What they don't have in current procedure is a price setting mechanism. But they do have a set of entry criteria which are based on share that are designed at least to meet one of our criteria, which is to narrow the universe.

But where we're stumbling is not on whether or not we agree with what Chantal referred us to on page nine, but the next step. Which is having created the class how do you price it?

DR. NEWHOUSE: Yes.

MR. HACKBARTH: So we're prepared to say that the threshold criteria are moving in the right direction. It begs the question of how to set the price. We don't have a definitive answer to that, but it ought to be a national rate that's non-inflationary in the mechanism.

DR. NEWHOUSE: And we're taking Sheila's point that you should think about this for the inpatient side as well.

MR. DEBUSK: Let's take a break.

MR. HACKBARTH: Do you have that in terms of what we're trying to capture? I'm not sure that every word or phrase of that needs to be in the boldface recommendation. Some of it can be relegated to the text. I'd be happy to talk to you about which is which, but that's the essence of the message.

DR. REISCHAUER: Not to go back to Capistrano and the swallows here, but I'm not sure that what you've described here is a very stringent test at all. It has to be 25 percent of the APC and exceed the thing it replaced by 25 percent. Well, if the thing it replaced was 25 percent of the APC, you're talking about the marginal cost is 7 percent of whatever the APC is, which strikes me as a pretty easy swallow.

DR. WORZALA: The next criterion on page nine is 10 percent of the total payment rate. So you're right about the 7 percent. 7 percent wouldn't cut it. It has to go up to 10 percent. We can say 10 percent isn't enough, but I guess it would depend if

your APC is $10,000 or $100.

MR. DEBUSK: Some of this new technology, some of these devices, I mean what's that new stent? That new stent is what, $1,900 a piece and it usually takes two per procedure. So you've got to be careful when you're putting a cap on top of an existing rate.

DR. ROWE: No, they're talking about a minimum, not a cap. They're talking about it's got to cost at least X in order to qualify, not putting a cap on it.

MR. HACKBARTH: I think it's beyond our purview to try to pass judgment on specific numeric thresholds. I wouldn't want to do that. We need to make directional statements, as opposed to numeric statements here. We could talk about this for the next year and not get consensus on specific numbers.

Okay, we're going to take a brief break, 15 minutes. We'll reconvene at 3:30.

Paying for new technology in the outpatient prospective payment system - January 17, 2002
Chantal Worzala, Dan Zabinski

DR. ZABINSKI: Yesterday we talked about a single draft recommendation, but what Chantal and I ultimately decided was to break this into two recommendations because we thought including all the points that we discussed yesterday made a single recommendation a little bit unwieldy. But the two recommendations you have are on a single handout so you can see them at the same time. They fit very much together.

The first recommendation says, the Congress should replace the hospital-specific payments for pass-through devices with national rates to be set by the Secretary. Also, the Congress should give the Secretary authority to consider alternatives to average wholesale price when determining payments for pass-through drugs and biologicals.

The next recommendation says, the Secretary should ensure additional payments are made only for new technologies that are expensive in relation to the applicable APC payment rate. Also, the Secretary should avoid basing national rates only on cost as reported by manufacturers. Finally, the Secretary should ensure that new technology payments for inpatient and outpatient services are based on the same principles.

DR. STOWERS: I have a little bit of a concern about the second one on the second recommendation, avoid basing national rates only on cost as reported by manufacturers. I think that might be something to talk about in the text but it sounds -- it kind of infers that their pricing may not be appropriate or something like that.

DR. NEWHOUSE: No, it just says -- what we want to say is, don't use cost reimbursement. And I'm actually not sure why

we're saying only. Just, avoid basing rates on cost.

DR. STOWERS: I think it could be interpreted a lot different than that is what I'm saying. That point I don't think is coming across clearly as to what our discussion was.

MR. HACKBARTH: Other comments?

DR. BRAUN: Not on that, but I wondered whether expensive standing by itself is enough, or whether we should have significantly expensive or something of that sort in that first...

DR. NEWHOUSE: Glenn, should we say, as reported by manufacturers or hospitals since we were talking about acquisition cost also?

MR. HACKBARTH: Yes, I think actually it was more the hospitals we were talking about as opposed to the manufacturers.

MR. DEBUSK: Should that not be, ensure additional payments are made only for new technologies and substantially improved technologies? Isn't that what we had in some prior language?

MR. HACKBARTH: Right, we did. Let me just step back from this for a second. As I thought about the discussion yesterday one of the concerns I had was that we were repeating things that were basically happening already. As I understand the current situation, the criteria for the pass-through are being tightened, using both cost and clinical standards. Now they may be imperfect criteria, but that's already going on. That was one of the things that we wanted to see happen and it was happening.

The second big issue we had was, when something does qualify for the pass-through, how do you pay for it? There was strong opinion that we needed to avoid a mechanism that was essentially a cost reimbursement. Try as we might, however, we've been unable to come up with a specific alternative at this point.

I would like to avoid being gratuitous in our bold-face recommendations. So one thought I had after yesterday's discussion was that in the text we could reinforce everything that's already happening and say, rah, rah, rah, this is going in the right direction. Then in the bold face simply say that the big, outstanding problem we see is how do we set rates for the pass-through items and we strongly recommend that it be done in a way that is not cost reimbursement.

Then if as a Commission we wish to pursue the issue further and try to come up with a specific mechanism we can do that for the future. So try to pare this down to what's really new and different. Does that make sense to people? Do people feel comfortable --

DR. NEWHOUSE: Is there any danger that the course that we're on would change? What you're saying is, we're on the course so we don't need to endorse the course. But that would be true if we're firmly locked into the course.

MR. HACKBARTH: In the text again I would say, we think this is the right direction to be going. We support tightening up the criteria, both using clinical and cost. The one thing that is

outstanding that really concerns us though is how you pay for the items that do qualify, and that's a bold-face recommendation.

DR. NEWHOUSE: I take that point. But on the first point the question is, is there going to be any effort to prevent or slow down the tightening?

MR. MULLER: I share Joe's concern because that's what happened last time. There was a smaller list and it got a lot bigger. That's what, at least my understanding is part of the reason we went from the 2.5 to 13, or let's say we exceeded the 2.5.

MR. DEBUSK: I think that's exactly right.

MR. MULLER: That's why I think the language that's in the bullet point, the first bullet point of point two is an important bullet point that reflects yesterday's discussion.

MR. HACKBARTH: If there are even a few commissioners that feel strongly about it then I think we ought to go with the bold-face language for the whole thing.

Okay, so we've had two amendments offered; Bea suggesting that we ought to have some modifier of expensive to highlight that we're talking about really expensive, which can be done in the text. My preference as opposed to adding lots of adverbs to pound the table in the recommendation is just in the text to emphasize that we think that needs to be a tight standard. Is that okay with you, Bea?

DR. BRAUN: Yes.

MR. HACKBARTH: Then the other issue that I've heard so far was in the next bullet, and the proposal was to add hospitals.

DR. NEWHOUSE: I'm just wondering if we could strike only, we could strike as reported by manufacturers. So it would say, avoid basing national rates on cost.

MR. HACKBARTH: I always prefer simpler over more wordy. Does that sound right to people?

MR. DEBUSK: Cost only perhaps.

DR. NEWHOUSE: I wouldn't use cost at all. I would just say, avoid basing national rates on cost. I'm not sure what only buys us.

MS. BURKE: I think, Joe, the question is what is CMS capable of doing? If we explicitly prohibit them using cost as a base, do they have the capacity at this time to have another method?

DR. NEWHOUSE: They don't use cost, for example, for erythropoietin.

MS. BURKE: Right. But in the case of, as was noted yesterday, one of the issues and the problems here is that we don't have any history on at least the new technologies. So there is little in the way of -- I mean, EPO has been out there for a while so we're playing in --

DR. NEWHOUSE: Yes, but at one time it was new.

MS. BURKE: At one time it was new. But if we explicitly prohibit cost you go to -- I guess the question is, what does CMS

go to?

DR. ROWE: Whose cost is this, Sheila? Is this the cost to the manufacturer, the hospital?

MS. BURKE: In Joe's system it's the manufacturer's cost --

DR. NEWHOUSE: I want to get rid of cost, so I don't care whose cost it is.

MS. BURKE: That's what I'm saying. He doesn't care whether it's the manufacturer's or the hospital's. Joe wants to do away with cost. My question is, what's the alternative if we prohibit these costs?

MR. HACKBARTH: That's the crux of the problem here. By definition we're talking about things that are new and for which we have little information. At least part of the motivation for the pass-through, as I understand it, was because we didn't have the information to fold them immediately into the APC rates we were going to have to pay for them on another basis while we collected the data. Now we're saying, we don't like that system, for very good reasons, and there needs to be an alternative but we don't know what it is. We only know what we don't want, which is a cost-based system.

That's a bit of a dilemma there. If we knew the right answer we could even, setting aside administrative issues, skip the interim step of a pass-through and just put it into the APC rates. If we knew the right answer right from the outset. But we don't know the right answer.

MR. MULLER: And if you could anticipate the technology. It's not just a price issue. It's also a --

MR. HACKBARTH: I'm saying, once it's here, if we know what the right rate is to pay for it we don't need to have a pass-through, we can just fold it into the rates, once it's here and --

MR. MULLER: If you could change the APCs every day of the year. And that's why you have a pass-through, because you can't change them every day of the year.

MR. HACKBARTH: That is the administrative reason. There is a process required to actually update these things so the pass-through is an administrative mechanism as well. But we're not going to resolve today how to set the rates. I think all we can say at this point is they should not be based on cost. And if we think this is a really important issue we can have staff work on it for the future and try to help CMS come up with an alternative approach. So I think that's where we stand.

If there aren't any other amendments --

DR. NEWHOUSE: I guess I'd observe that we've put in place all the post-acute prospective payment systems to get away from cost reimbursement in post-acute. Not that I want to hold that up as a shining example of what might happen here, but we certainly have put systems into place that we didn't know what was going to be in place when we got downstream. We just said, do this. I mean, there was an interim system, obviously.

MS. BURKE: I'm sorry, Glenn. I don't mean to belabor this because I don't disagree with Joe's fundamental point, which is to move away from an inflationary system. Even in those cases, as flawed as they are, there was some history in the context of services we provided and the cost of those services. In this case we are in fact trying to anticipate what some thing or a process will cost going forward so that we can incorporate it into a payment system.

While we want to get away from a model that essentially has the incentive to have it be the most expensive; i.e., put it into the base. In the absence of a reference to cost I'm perfectly willing to let it be left to everyone's guess, but frankly, I don't know what the guess is. Is it the return on equity as you talked about equity? That raises a whole series of other issues. I don't think we can go there.

DR. NEWHOUSE: Not today.

MS. BURKE: Not today. So I'm happy to leave it vague, don't do it on cost. But my only question will be the natural one and the staff then will have to sort out is, okay, what else? What is there?

MR. HACKBARTH: Sheila, would you prefer, based only on cost? So you would prefer only being in there?

MS. BURKE: I guess I would prefer to leave the only in, just as a modifier, until we get a handle. If staff can come up with some great alternative I'm all for it. Because I'm just where Joe is, which is, we don't want to build a system going forward that encourages everybody to be the most expensive they can be. I absolutely agree.

DR. NEWHOUSE: My problem with only is that it sounds like what we want is a system that's partially cost and partially something else. That's how I read, avoid only on cost.

MR. HACKBARTH: I think we could explain in the text that ideally you disconnect, but it may be a necessary starting point that we use some cost information. We don't want to rule that out I think is what Sheila is saying.

MR. MULLER: So we can say, based on discredited pre-prospective price --

MS. BURKE: Inflationary.

[Laughter.]

MR. HACKBARTH: In the text. We'll say that in a footnote.

DR. NEWHOUSE: It's also not clear that -- I don't want to belabor the point -- that we wouldn't have some information. In several cases I could imagine that there would be out there in the market before Medicare makes a coverage decision and then we would in fact have some information.

DR. REISCHAUER: Maybe we should drop this bullet completely because we don't seem to know what it is that we're suggesting.

DR. NEWHOUSE: Glenn didn't want a negative in a recommendation as I heard Glenn, but in fact I think the temptation to use cost reimbursement is so strong I'd like to see

it in bold-face.

MR. HACKBARTH: I think we are at the point of belaboring this point. I don't think we're advancing the discussion over where we were yesterday. So what I would suggest is that we leave only in, just to give some flexibility as Sheila has proposed, and then move as quickly as possible to a vote on this. We do have skilled nursing still to deal with and we've got some preparatory work on our June report. So we're running out of time here.

Any really urgent --

DR. WAKEFIELD: It's urgent to me, of course. Glenn, are these additional payments -- I raised this question yesterday but I had to step out of the last part of the conversation. Are we doing this in a budget neutral fashion? I want to raise that again. Is there budget neutrality in play here?

MR. HACKBARTH: Yes.

MR. MULLER: That's the current law.

DR. WAKEFIELD: Then I'd like to ask, just in text, that we have some brief discussion of how that impacts hospitals with different case mix. So in other words, that's going to have a -- that will distort or impact the relative weights of, for example, rural hospitals that may not be users of that technology if the payment is budget neutral.

MS. BURKE: Mary, this isn't new.

DR. WAKEFIELD: I know.

MS. BURKE: You just want to restate the law.

DR. WAKEFIELD: Exactly. I know pass-through payments, I know that's not new, and I know the impact. Part of the reason I'm asking this is because we getting pretty close to the phase-out of the hold harmless and we've got lots of things going on with those hospitals. So I'd just like that reiteration in the text if that's acceptable.

MR. HACKBARTH: So it's descriptive of the consequence.

DR. WAKEFIELD: Exactly. Not asking for anything new. Just a reiteration.

MR. HACKBARTH: Anything else before we vote?

Okay, we'll do the two in order. First, the Congress. All opposed, raise your hands, please.

All in favor?

Abstain?

Then the second --

MR. DEBUSK: Glenn, one last question on the second one. That substantially improved, does that statement go in there as well, new technologies and substantially improved technology? That's in the second one.

DR. ZABINSKI: Can you just say new or substantially improved technologies?

MR. DEBUSK: Exactly.

MR. HACKBARTH: So the second bullet would be, avoid basing rates only on cost.

All opposed to the recommendation as amended?
All in favor?
Abstain?
Okay, thank you.

DR. ROWE: From a clinical point of view substantially improved is important, because like the example we had yesterday, the stents, now they're coating them with some agent that prevents blood clots. Many people would argue, that's not a new technology; we had stents before. But it's obviously an improvement. So I think that's worth making sure that it's commented on.